

REMARKS**I. Claim Status:**

Claims 23, 24, 27, 29-34, 43, 44, 47-63, and 65 have been canceled, without prejudice or disclaimer subsequent to their withdrawal from consideration by the Examiner as being directed to non-elected subject matter. Applicants reserve the right to pursue the subject matter of the canceled claims in one or more divisional applications.

Claims 1-22, 25, 26, 28, 35, 37-39, 64, and 66-85 are pending and at issue.

II. Examiner Interview/Election of Alternative Species for Initial Examination

The Examiner is thanked for the courtesies extended during a June 30, 2005 telephone interview with the undersigned agent. During the interview, it was agreed that, in view of Applicants' intent to delete the previously elected species (SEQ ID NO: 219) from the sequence listing, Applicants would elect an alternative species for prosecution on the merits should no generic claim be finally held to be allowable.

Accordingly, Applicants hereby elect the species of the Der p 2 allergen with the mutations K15E S24N H30G K48A E62S K77N K82N K100N (see specification at page 97, line 34 through page 98, line 1) for prosecution on the merits if no generic claim is finally held to be allowable. The full sequence of the elected species is set forth in the sequence listing as SEQ ID NO: 36.

III. Anticipation Rejections

A. Rejections Under 35 U.S.C. § 102(e)

Claims 1-22, 35, 64, and 66-82 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Application Serial No. 10/719,553 (“the ‘553 application;” published as U.S. Publication No. 2004/0091500). According to the Examiner, the ‘553 application discloses some of the same Bet v 1 mutants as disclosed and claimed in the present application. This rejection is fully traversed on the grounds that the ‘553 application does not disclose the presently claimed invention.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131.01 (citing *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the patent claim.” MPEP § 2131.01 (citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)).

Claim 1 is directed to a recombinant allergen, in which at least four primary mutations are spaced from each other by at least 15Å. The ‘553 application does not disclose the claimed recombinant allergens. In fact, the ‘553 application is silent as to the spacing of mutations on recombinant mutant allergens. Therefore, the ‘553 application fails to disclose the present claim limitation of a recombinant mutant allergen comprising at least four mutations spaced from each other by at least 15Å. Moreover, the only example of a recombinant allergen having at least four mutations disclosed in the ‘553 application is a Bet v 1 mutant with the following four mutations: Asn28Thr, Lys32Gln, Glu45Ser, and Pro108Gly. *See* ‘553 application at ¶ 0109; SEQ ID NOS: 36 and 37. The distance between the mutations at the 28 and 32 amino acid positions is only 7.47Å. Thus, at least two of the mutations in the recombinant allergen exemplified in the ‘553

application are positioned closer to each other than the required distance of “at least 15Å,” as recited in claim 1. Therefore, the ‘553 application fails to anticipate the present claims because it does not disclose a recombinant allergen having at least four primary mutations spaced at least 15Å from each other.

The ‘553 application does not disclose the claimed invention. The present rejection should therefore be withdrawn. Reconsideration of claims 1-22, 35, 64, and 66-82 and the withdrawal of the rejection thereof under 35 U.S.C. § 102(e) is requested accordingly.

B. Rejections Under 35 U.S.C. § 102(f)

Claims 1-22, 35, 64, and 66-82 have been rejected under 35 U.S.C. § 102(f) because the inventive entity of the ‘553 application differs from the inventive entity of the present application, and, according to the Examiner, both applications claim the same subject matter.

As set forth above with reference to the rejection under 35 U.S.C. § 102(e), the ‘553 application does not disclose the presently claimed invention. Therefore, this rejection should be withdrawn.

C. Rejections Under 35 U.S.C. § 102(b)

Claims 1-22, 35, and 64-82 have been rejected under 35 U.S.C. § 102(b) as anticipated by International Publication No. WO 99/47680 (“WO ‘680”). WO ‘680 is the international counterpart of the ‘553 application; and both applications have the same disclosure. Accordingly, for the reasons set forth above with reference to the rejection under 35 U.S.C. § 102(e) and the ‘553 application, WO ‘680 does not disclose the presently claimed recombinant allergens, in which at least four primary mutations are spaced from each other by at least 15Å. Therefore, this rejection should be withdrawn.

IV. Obviousness-Type Double-Patenting Rejection

Claims 1-22, 35, 64, and 66-82 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 13-27 of the '553 application. In response and without conceding the validity of the present rejection, Applicants note that, prior to issuance of the Office Action to which ~~this~~ amendment responds, claims 13-27 of the '553 application ~~were~~ canceled in a Preliminary Amendment filed December 21, 2004 (copy attached as Exhibit A). Therefore, this rejection should be withdrawn.

V. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 4-14, 16, 18, 25, 26, 28, 35, 37-39, 64, 68-80, and 83-85 have been rejected under 35 U.S.C. § 112, first paragraph, as not being supported by the written description with respect to SEQ ID NO: 219. In response, it is noted that SEQ ID NO: 219 does not appear in the rejected claims. Thus, the present rejection is unwarranted. Moreover, without conceding the validity of the present rejection, and in response to the rejection under 35 U.S.C. § 132 (further discussed below), SEQ ID NO: 219 has been removed from the specification. *See* Amendment to Sequence Listing Under 37 C.F.R. § 1.825, filed concurrently herewith. Therefore, the present rejection is moot.

VI. Rejections Under 35 U.S.C. §132

The Amendment filed June 30, 2004 has been objected to under 35 U.S.C. § 132 for including the addition of SEQ ID NO: 218 and 219. In response and without conceding the validity of the present rejection, SEQ ID NO: 218 and 219 have been removed from the specification and do not appear in any of the pending claims. *See* Amendment to Sequence

Listing Under 37 C.F.R. § 1.825, filed concurrently herewith. Therefore, this rejection should be withdrawn.

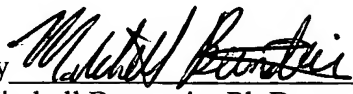
VII. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: July 5, 2005

Respectfully submitted,

By 

Mitchell Bernstein, Ph.D.

Registration No.: 46,550

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant